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EXAMINER	
WHALEY, PABLO S	
ART UNIT	PAPER NUMBER
1631	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,636	RAMBAUD, PATRICK	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,34 and 36-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,34 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request For Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/14/2009 has been entered.

Status of the Claims

Claims 33, 34, and 36-42 are rejected.

Claims 33, 34, and 36-42 are pending.

Claims 1-32 and 35 are cancelled.

Objections

Claim 33 is objected to because of the following informalities: Claim 33 (line 33) is grammatically incorrect, and should recite "...information that is characteristic..." . Appropriate correction is required.

Claim 41 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, claim 41 depends from itself. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Withdrawn Rejections

The rejection of claims 1, 15-18, 20, 25, 30-33, and 35 are rejected under 35 U.S.C. 103(a) as being made obvious by Lefesvre et al. is withdrawn in view of applicant's amendment filed 07/14/2009.

The rejection of claims 1, 2, 15-18, 20, 21, 25, and 30-35 are rejected under 35 U.S.C. 103(a) as being made obvious by Lefesvre et al. in view of Cha et al. is withdrawn in view of applicant's amendment filed 07/14/2009.

The rejection of claim 1 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,415,201 (Issued Jul. 2, 2002) is withdrawn in view of applicant's amendment filed 07/14/2009.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36-42 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

The claims are drawn to a method for managing batches of cells collected from humans or animal subjects for their deferred use. A claimed process is statutory under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter), or (2) it transforms a particular article into a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008; In re Comiskey, Fed. Cir., No. 2006-1286).

Regarding the required tie to a particular machine or apparatus, the process required by claims 36-42 are not limited to a particular apparatus or machine. For example, the claimed subject matter requires steps for collecting data, generating data, implementing a process for determining a deferred use protocol into an expert system, determining parameters, using data stored in a database, extracting cells from a library, and processing cells. The claims do not recite any specific machines for carrying out these steps. To qualify as a statutory process, the claims should require use of a machine within the steps of the

claimed subject matter or require transformation of an article to a different state or thing. Insignificant data gathering or post-solution activity (e.g. extracting and processing cells, conditioning and preserving cells) in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants may overcome the rejection by amendment of the claims to perform critical steps of the claimed invention using a specific computer, device, or processor having structure. The applicants are cautioned against introduction of new matter in an amendment.

Regarding the transformation test, the claimed subject matter does not recite a physical transformation of matter. For example, the claimed subject matter requires steps for extracting and processing cells from a library, as well as conditioning and preserving cells but does not require performing these steps with specific assays [See In re Grams, 12 USPQ2d 1824 (Fed Cir. 1989)]. This rejection could be overcome by amendment of the claims to recite a step wherein an article is reduced to a different state or thing (e.g. physical assay), or a step wherein data representing a physical object or substance that is obtained by a specific physical process is sufficiently manipulated or changed (e.g.. raw data into a particular visual depiction of a physical object on a display) [See In re Abele, 684, F.2d at 908-909, CCPA, 1982]. The applicants are cautioned against introduction of new matter in an amendment.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claims 33 and 36 are also rejected due to said dependence.

Claim 33 (5th line from the last) recites "optimal proportions of various selected types of cells." The term "optimal proportions" implies that proportions of cells are chosen by some existing criteria. However, the specification does not provide a standard or criteria for optimal proportions such that one of ordinary skill in the art would know the metes and bounds of optimal proportions, as claimed. Clarification is requested.

The term "optimal proportions" in claim 33 (5th line from the last) is a relative term which renders the claim indefinite. The term "optimal proportions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular, the parameter of selected types of cells has been rendered indefinite by the use of the term "optimal proportions."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33, 36, 37, 38, 39, 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), and in view of Shortliffe et al., (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881; IDS filed 09/12/2006).

Claims 33, 36, 37, 38, 39, 41 are drawn to a method and system for managing batches of immunocompetent cells collected from human or animal subjects for their deferred use. The components of the invention include a storage device, collection device, status-characterizing device to determine identity data, a cell management processor for storing identity data, a personal library processor for constituting a personal library.

Lefesvre teaches batch management system for managing immunocompetent lymphocyte cells obtained from human subjects [p. 1, ¶1]. In particular, Lefesvre teaches one or more cryogenic storage sites wherein each batch of immunocompetent cells are collected, stored, and preserved for deferred use [p.2, ¶7, ¶8, p. 3]. The information collected for processing includes personal data relating to the subject, cellular identification data, immunity related information, and gene therapy protocol information [p.2, ¶8, p.2, ¶ 12, Fig. 1, p.3, p.4, ¶5]. Lefesvre teaches processing of blood to collect information indicative of

patient health status [p. 1 and Fig. 1, p.3, ¶ 9], which shows a status characterization step of collecting information. A plurality of cellular processing centers are described for batch processing of immunoqualified cells [p.3, ¶1]. The centers provides means for communicating with storage sites, producing a personal library of immunoqualified lymphocyte cells, which inherently store immunity information, and identifying stored batches of cells in response to requests for treatments using said cells [p.3, ¶1, See also p.2, ¶ 2, p.4, ¶ 4]. Lefesvre provides a database that can be queried by a user to obtain information [p.3, last ¶]. Lefesvre teaches protocols for performing identification of cells and consulting a cell management database system[p.3, ¶1-¶3, p.4, ¶1], receiving requests for subject identity data [p.3, last ¶], and processing of the database based on patient specific requests [p.4, last ¶, p.4]. Lefesvre shows a process for selecting and removing cells from a personal library according to deferred use protocols and components for re-using lymphocytes in the patient [p.4, ¶ 2, and p.4, ¶7 onwards], which shows selecting cells for extraction. Lefesvre describes steps for gathering personal data for processing at the time of re-use [p.4, ¶5]. The system makes possible the batch storage of cells in accessible and identifiable form for deferred use protocols including gene therapy protocols, restoring cellular immunity, gene therapy, genetic analysis, infection detection, etc. [p.2, ¶6, p.2, ¶ 12, p.4, ¶8, p. 3]. Lefesvre teaches checking operations of quality (i.e. checking for annihilation of antibodies) [p.4, ¶ 2]. The overall management process is achieved using software [p.4, last ¶].

Lefesvre does not teach an expert system wherein said information is entered in the form of biological items to which a set of rules stored in a knowledge base is applied, as in claims 33 and 36.

Lefesvre does not teach implementing into said expert system a process for determining a deferred use protocol comprising biological and technical indications required for cell processing before re-use of a batch of immunocompetent cells, as in claims 33 and 36.

Lefesvre does not teach a processor for processing identity data to determine parameters of a deferred use protocol, said processor configured on prescription of a re-use process, as in claims 33 and 36.

Shortliffe teaches an expert system for clinical protocol management. In particular, the expert system (ONCOCIN) comprises a data-acquisition program (Interviewer) for obtaining and reviewing patient data, and a consulting device (Reasoner) for providing recommendations on the appropriate tests and therapies (i.e. deferred use protocols) [p.877, Col. 2]. The Reasoner obtains data from a knowledge base that stores patient information, previous treatments, laboratory results, and protocol specific information [p.877, Col. 2, ¶2]. Specific rules for determining deferred uses are disclosed [p.879, Col. 1, Col. 2, Advice]. Standard procedures for determining parameters for protocol management and parameter values are also described [p.878, Col. 2, ¶4, p.879, Col. 2, Control]. The system is flexible and easily modified to address different types of protocols [p.881, Col. 1, ¶1, ¶2].

Barnhill teaches an expert system for receiving patient data from another location, processing the data to produce a diagnostic or prognostic value, and transmitting the result to another location [Abstract, Col. 7, ¶4, Fig. 12]. The expert system uses patient information, biomarkers, demographics, and physiological measurements information [Col. 7, ¶4, Fig. 13A]. Specific ranges for disease are described and used in the treatment recommendation process [Fig. 17].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system of Lefesvre by using an expert system wherein said information is entered in the form of biological items to which a set of rules stored in a knowledge base is applied, as in claim 33, since Shortliffe shows a modifiable expert system that uses biological information and rules for making treatment recommendations (i.e. deferred use protocols) with predictable results, as set forth above, and since Lefesvre provides specific biological information and deferred use protocols for use with a processing system [p.2, ¶6, ¶8]. The motivation would have been to improve treatment

recommendations with an automated consultation system that optimizes the use of patient data [Shortliffe, p.881, Section VII].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system of Lefesvre by implementing into said expert system a process for determining a deferred use protocol comprising biological and technical indications required for cell processing before re-use of a batch of immunocompetent cells, as in claim 33, since Barnhill provides an expert system for making recommendations using data from remote locations, as set forth above, and since Shortliffe shows a modifiable expert system that uses biological information for making treatment recommendations (i.e. deferred use protocols) with predictable results, as set forth above. The motivation would have been to provide physicians with an improved system for data collection and decision making [Shortliffe, p.881, Section VII].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system of Lefesvre by processing identify data to determine parameters of a deferred use protocol, as in claim 33, since Shorliffe shows parameters relevant for deferred use protocols used in processing patient data [p.877, Col. 2, ¶2, p.878, Col. 2, ¶4, p.879, Col. 1, Col. 2, Advice]. The motivation would have been to improve treatment recommendations with an automated consultation system that optimizes the use of patient data [Shortliffe, p.881, Section VII].

Claims 33-34 and 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), and in view of Shortliffe et al., (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881), and further in view of Zanin et al. (WO/1997/045056; Publication Date: 12/4/1997) and Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137).

Lefesvre, Barnhill, and Shortliffe make obvious a method and system for managing batches of immunocompetent cells for deferred use, as set forth above.

Lefesvre, Barnhill, and Shortliffe do not teach a device for collecting bioelectronic information, as in claims 34.

Lefesvre, Barnhill, and Shortliffe do not teach bioelectronic information resulting from processing measures as in claim 40.

Zanin teaches a method and device for measuring, processing, and storing bio-electrical signals [Abstract, p.2, Fig. 1, p.6]. Collected and processed information includes parameters and data relating to various measured levels including pH [p.9, last ¶]. In addition, Zanin also teaches an expert system comprising control and interpretation software to provide the physician with tools for determining patient health status and reliable treatments [Abstract, p.3, Ref. claims 3 and 5].

Cha teaches a routine method for obtaining bioelectronic information by processing previously collected patient blood samples. The information includes resistance (i.e. resistivity) and reactance data [Abstract, Fig. 1, Section 3], as in claims 2, 21, and 34.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system taught made obvious by Lefesvre, Barnhill, and Shortliffe by collecting bioelectronic information, as in claims 34 and 40, since Zanin and Cha shows methods and devices for storing an processing bioelectronic data, as set forth above. The motivation would have been to improve patient care using a system adapted to receive and analyze bioelectronic data commonly used in patient health assessment, as suggested by Zanin [p.1, ¶3] and Cha et al. [p.136, ¶ 3and 4].

Claims 33, 34, and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), in view of Shortliffe et al., (In Proc. Seventh International

Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881), in view of Zanin et al. (WO/1997/045056; Publication Date: 12/4/1997), in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137), and further in view of Tomoyasu (Applied And Environmental Microbiology, Jan. 1998, p. 376–382).

Lefesvre, Barnhill, Shortliffe, Zanin, and Cha make obvious a method and system for managing batches of immunocompetent cells for deferred use, as set forth above.

Lefesvre, Barnhill, Shortliffe, Zanin, and Cha do not teach a step for immunomagnetically selecting purified lymphocytes or monocytes, as in claim 42.

Tomoyasu teaches a method for immunomagnetically separating cells using Dynabeads [Abstract].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system taught made obvious by Lefesvre, Barnhill, Shortliffe, Zanin, and Cha by immunomagnetically selecting purified lymphocytes or monocytes, as in claim 42, since Tomoyasu shows conventional methods of immunomagnetic separation of cells, as set forth above. The motivation would have been to provide an improved method of separating cells using magnetic beads [Tomoyasu, p.379, Col. 1, ¶3, ¶4].

Response to Arguments

Applicant's argument filed 05/14/2009 have been fully considered but are not persuasive for the following reasons.

In response to applicant's argument that Lefesvre does not teach determining a protocol of deferred use for immunocompetent cells from identified batches, by processing said subject's identity data received from a cell management database, Lefesvre teaches a process management system that allows for identifying batches of cells for re-injection into patients, for example, as set forth above.

In response to applicant's argument that LEFESVRE does not teach deriving the subject's identity data by collecting information characteristic of the status of the subject's health and/or the psychological status by processing measurements made on cell samples, it is noted that the features upon which applicant relies (i.e., deriving the subject's identity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's argument that LEFESVRE does not teach constituting from the collected cells, a personal cell library of immunocompetent cells containing a sum of immunity information stored in the membranes of the collected immunocompetent cells for determining the subject's identity data including immunity related data, historical and clinical data on previous diseases, treatments and therapeutic protocols experienced by said subject are moot in view of the new grounds of rejections.

Applicant's argument that LEFESVRE does not teach gathering status-characterizing information obtained by processing measurement made on the subjects samples are moot in view of the new grounds of rejections.

In response to applicant's argument that LEFESVRE does not teach processing status-characterizing information to obtain identify data, Lefesvre teaches processing of blood to collect information indicative of patient health status [p. 1 and Fig. 1, p.3, ¶ 9].

In response to applicant's argument that LEFESVRE does not teach storing the subjects identity data and performing an identification of batches of cells by consulting said cell management database, Lefesvre shows a plurality of cellular processing centers that provide means for communicating with storage sites, identifying stored batches of cells in response to requests for treatments using said cells, and means for querying a database to locate batches [p.3, ¶1, p.3, last ¶, See also p.2, ¶ 2, p.4, ¶ 4].

Applicant's argument that LEFESVRE does not teach receiving the subjects identity data from said cell management database upon receiving a request from a treatment facility are moot in view of the new grounds of rejections.

In response to applicant's argument that LEFESVRE teaches away from the instant invention, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lefesvre teaches batch management system for managing immunocompetent lymphocyte cells for deferred use [p. 1, ¶1], and therefore is reasonably pertinent to the particular problem with which the applicant is concerned.

Applicant's argument that no motivation has been provided to suggest the combination of Lefesvre and Chu is moot in view of the new grounds of rejections.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

/PW/

/SHUBO (Joe) ZHOU/
Primary Examiner, Art Unit 1631